

REMARKS

Claims 1-4 are currently pending in this application, with claims 9-21 being withdrawn. Applicants have amended claim 2. Support for this amendment is found in the specification on page 8, Table 2. No new matter is being presented by this amendment.

**A. Rejection under 35 U.S.C. § 112, first paragraph**

Claims 1-14 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the preparation of the crystalline compounds with the specific DSC and IR spectra found in Figures 1 and 2 of the specification, does not reasonably provide enablement for any crystalline monohydrate of tiotropium bromide. Applicants traverse.

In order to support a rejection under 35 U.S.C. §112, first paragraph, for lack of enablement, the burden lies first with the Patent and Trademark Office (PTO) to provide evidence or objective reasoning substantiating the allegation that the enabling disclosure is not commensurate in scope with the claims. In re Marzocchi et al., 169 USPQ 367 (CCPA 1971). As stated in Marzocchi,

".. a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112, unless there is reason to doubt the objective truth of the statements contained therein..",

and further,

"..it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." (emphasis original).

Applicants have taught how to make and use crystalline tiotropium bromide monohydrate. Unless there is evidence to the contrary, applicants' teaching of making this particular compound enables them to the full scope of this claim.

**B. Rejection under 35 U.S.C. § 112, second paragraph**

Claims 1-4 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, applicants have amended claim 2 to further define the monoclinic crystalline tiotropium bromide monohydrate by a space group of P 2<sub>1</sub>/n.

**C. Double Patenting**

Claims 1-4 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,777,423 B2. In response, applicants have filed a terminal disclaimer concurrently herewith, thus rendering moot this rejection.

**D. Conclusion**

In view of the above amendments and remarks, applicants respectfully request that Examiner pass this application to issuance. If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

/wendy petka/

Wendy Petka, Reg. No. 53,459  
Attorney for Applicants

BOEHRINGER INGELHEIM CORPORATION  
Patent Department  
900 Ridgebury Road  
P.O. Box 368  
Ridgefield, CT 06877  
Telephone: (203) 791-6614  
Facsimile: (203) 798-4408